

REMARKS

Please note the change in representation in the instant application.

Numerous minor grammatical corrections have been made to the claims as currently pending, including the correction of spelling, punctuation, and antecedent basis. It is believed that these amendments do not alter the scope of these claims.

In claims 71, 75, and 79, the terms “L-arginine chloride,” “L-arginine gluamate,” “L-arginine butyrate” and “L-arginine glutamate” have been deleted. In claims 73, 77, and 81, the terms “oleoresin” and “capsicum” have been deleted.

The phrase “topically treating a medical condition,” which appears only in the preambles of claims 64-67 and 69, has been deleted.

The term “bedsores” has been replaced by “bed confinement” in claim 64. This amendment finds support in the specification, for instance, in Paragraph 0002. (The paragraph numbers of the specification recited in this response are in reference to the substitute specification filed March 29, 2004, which was accepted and entered by the Patent Office, as noted by the currently pending Office Action mailed December 14, 2004).

Claim 64 has also been amended to recite that the means of delivering the substance is selected from the group consisting of topical creams, topical lotions, and topical ointments. Support for this amendment can be found in the specification, for example in Paragraph 0014.1.

The phrase “alkyls of L-arginine” in claim 67 has been deleted. Claim 68, which also recited this phrase, has been canceled without prejudice or disclaimer.

The phrase “growth rate and repair of cells” in claims 33 and 70-73 has been deleted.

In claims 33, 42, and 51, the phrase “combined with a concentration of an agent sufficient to” has been replaced by the phrase “combined with an agent for creating a hostile biophysical environment at a concentration sufficient to” to clarify that the agent is the item that is combined. Similarly, in claims 39, 47, and 56, the term “concentration of ionic salt” has been replaced by “ionic salt at a concentration.”

In claims 71-73, 75-77, and 79-81, the term “agent” has been replaced by “agent for creating a hostile biophysical environment.” This amendment clarifies that the term “agent” in these claims is the agent that is able to create a hostile biophysical environment, recited in claims 33, 42, or 51, from which of these claims ultimately depends.

In claims 73, 77, and 81, the terms “high ionic strength environment,” “neutralization of L-arginine’s charge in a complex,” “inclusion in a liposome,” “high pH,” “low pH,” and “highly hydrophobic environments” have been deleted.

In claims 34, 35, 39-41, 47, 48, 49, 52, 56-59, and 66, the term “by weight” has been added, to clarify that the percentages recited are weight percentages.

No new matter has been added by these amendments. Claims 33-35, 38-44, 47-53, 56-59, 61-67, and 69-81 are now pending for examination.

Rejection of Claims 33-35, 38-41, 50, 64-73, 75-77, and 79-81 under 35 U.S.C. §112, ¶1

Claims 33-35, 38-41, 50, 64-73, 75-77, and 79-81 have been rejected under 35 U.S.C. §112, ¶1, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The Patent Office stated that the specification as filed does not disclose the terms “oleoresin,” “capsicum,” “neutralization of L-arginine’s charge in a complex,” “L-argini[n]e chloride,” “L-arginine glutamate,” or “L[-]arginine butyrate.”

Claims 71, 73, 75, 77, 79, and 81 have been amended to delete these terms.

The Patent Office has also stated that the specification as filed does not broadly disclose the terms “the method of topically treating a medical condition,” “superficial wounds,” “treatment of bed sores,” “sexual dysfunction,” “alkyls of L-arginine,” or “growth and repair of cells.”

Claims 33, 64-67, and 69-73 have been amended to delete the terms “the method of topically treating a medical condition,” “alkyls of L-arginine,” and “growth and repair of cells.” Claim 68 has been canceled without prejudice or disclaimer. With respect to the terms “superficial wounds” and “sexual dysfunction,” it is not seen where these terms appear in the claims. Regarding the term “bedsores,” this term has been replaced with “bed confinement.”

The remaining claims rejected on the grounds of 35 U.S.C. §112, ¶1 either depend from the above-mentioned claims, or do not recite these terms. It is therefore respectfully requested that the rejection of claims 33-35, 38-41, 50, 64-73, 75-77, and 79-81 be withdrawn.

Rejection of Claims 33-35, 38-41, 50, 70-73, 75-77, 79 and 81 under 35 U.S.C. §112, ¶2

Claims 33-35, 38-41, 50, 70-73, 75-77, 79 and 81 have been rejected under 35 U.S.C. §112, ¶2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

With respect to the term “agent,” claims 33, 42, 51, 71-73, 75-77, 79, and 80 have been amended to clarify that the agent is an agent for creating a hostile biophysical environment. Thus, withdrawal of the rejection of these claims is respectfully requested. However, it is believed that the term “agent,” as pending in the claims prior to the instant amendment, properly antecedently referred to the agent recited in claims 33, 42, and 51, from which each of these claims ultimately depended.

With respect to the term “concentration of an agent,” this term has been replaced by “an agent for creating a hostile biophysical environment at a concentration” in claims 33, 42, and 51. Thus, the “agent for creating a hostile biophysical environment” can be distinguished from, for example, a penetrating agent.

With respect to the terms “inclusion in a liposome,” “neutralization of L-arginine’s charge in a complex,” “high ionic strength environment,” “high pH,” “low pH,” and “highly hydrophobic environments,” these terms have been deleted from claims 73, 77, and 81, rendering the rejection of these terms moot.

In view of the above-identified amendments, it is believed that claims 33-35, 38-41, 50, 70-73, 75-77, 79 and 81 are patentable in view of 35 U.S.C. §112, ¶2, and it is thus respectfully requested that the rejection of these claims be withdrawn.

Rejections in view of Saavedra

Claim 64 has been rejected under 35 U.S.C. §102(b) as being anticipated by Saavedra, et al., U.S. Patent No. 5,632,981 (“Saavedra”). Claims 65 and 66, which each ultimately depend from claim 64, have been rejected in view of Saavedra under 35 U.S.C. §102(a) or, in the alternative, under 35 U.S.C. §103(a).

It is not seen where Saavedra recites topical creams, topical lotions, or topical ointments, as recited in claim 64, as amended. Instead, Saavedra refers to liquid solutions such as water or saline (column 11, lines 41-43), or phosphate buffer solutions (column 12, lines 49-55), but nowhere discloses or suggests topical creams, topical lotions, or topical ointments. Accordingly,

it is respectfully requested that the rejection of claim 64 be withdrawn. Claims 65 and 66 are believed to be allowable for at least the above-mentioned reasons, and withdrawal of the rejection of these claims is also respectfully requested.

Double Patenting Rejection

Claims 33-35, 38-41, 61, and 64-78 have been rejected under the judicially-created doctrine of obviousness-type-double-patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,207,713. However, the Patent Office stated that a timely filed Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome this rejection.

Without acceding to the correctness of this rejection, enclosed herewith is a Terminal Disclaimer with respect to U.S. Patent No. 6,207,713 in compliance with 37 C.F.R. §1.321(c) to overcome this rejection. In view of this Terminal Disclaimer, these claims are believed to be allowable. Withdrawal of the rejection of these claims is therefore respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after the foregoing amendments and remarks, that the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Serial No.: 08/923,227
Conf. No.: 5092

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Art Unit: 1711

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Docket No.: S1509.70029US00

Date: June 14, 2005
x06/14/05x